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[FR Doc. 95–19797 Filed 8–15–95; 8:45 am]
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40 CFR Part 180

[PP 2F4090/R2154; FRL–4966–9]

RIN 2070–AB78

Occlusion Bodies of the Granulosis Virus of Cydia Pomenella; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a pesticide tolerance for residues of the microbial pest control agent Occlusion Bodies of the Granulosis Virus of *Cydia pomenella* (codling moth) in or on all raw agricultural commodities. The University of California at Berkley requested this tolerance exemption in a petition submitted under the Federal Food, Drug and Cosmetic Act (FFDCA). This regulation eliminates the need to establish a maximum permissible level for residues of *Cydia pomenella* Granulosis Virus.

EFFECTIVE DATE: This regulation becomes effective on August 16, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 2F4090/R2154], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 2F4090/R2154]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 259, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8733; e-mail: hollis.linda@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 1992 (57 FR 24645), EPA issued a notice that The University of California, Berkley, CA 94720, had petitioned EPA under section 408 of the FFDCA, 21 U.S.C. 346a, to establish an exemption from the requirement of a tolerance for residues of the microbial pest control agent *Cydia pomonella* Granulosis Virus in or on all raw agricultural commodities when used to control the codling moth.

There were no comments received in response to the notice of filing.

The data submitted in the petition and all other relevant material have been evaluated. The toxicological data considered in support of the exemption from the requirement of a tolerance include the following: an acute toxicity/pathogenicity study, an acute dermal toxicity study, an acute intravenous toxicity study, a primary eye irritation study, and a cell culture assay.

1. *Acute Oral Toxicity/Pathogenicity in Rats, Guideline No. 152A-10.* Eighteen male and female rats were dosed by oral gavage with 5.0 mL *Cydia pomonella* granulosis inclusion bodies at a potency of 4 X 10^{11} GIBs/mL. No abnormalities or toxicity were observed. A distinct clearance pattern was evident in the feces and heart/lungs through day 7 of the study. TOX CATEGORY IV.

2. *Acute Dermal Toxicity in Rabbits, Guideline No. 152A-11.* Five male and female New Zealand rabbits were tested. One test animal displayed mild erythema and edema within 24 hours postdosing. No other signs of dermal irritation were noted. TOX CATEGORY IV.

3. *Acute Pulmonary Toxicity/Infectivity in Rats, Guideline No. 152A-13.* Thirty-four male and female Sprague-Dawley rats were dosed via intratracheal injection with 1.2 mL/kg GIBs/mL. Baculovirus *Cydia pomonella* was not toxic, infectious, or pathogenic to rats. TOX CATEGORY IV

4. *Primary Eye Irritation in Rabbits, Guideline No. 152A-14.* Six New Zealand white rabbits were administered in a single dose of 0.1 mL Baculovirus *Cydia pomonella* into the conjunctival sac of both eyelids. Baculovirus *Cydia pomonella* was not irritating to rabbit eyes when compared to rabbits treated with sterile distilled water. Ocular irritation dissipated in both control and treated eyes by day 21. TOX CATEGORY II.

5. *Cell Culture Toxicity/Infectivity, Guideline No. 152A-16.* Three human cell lines WI-38, WS1, and HepG2 were challenged with 2 X 10^9 particles/mL of *Cydia pomonella* Granulosis Virus (CpGV) over a 1-hour exposure and rinsed. No significant cytopathic or toxic effects were observed.

The toxicology data provided are sufficient to demonstrate that there are no foreseeable human health hazards likely to arise from the *Cydia pomonella* Granulosis Virus in or on all raw agricultural commodities when applied in accordance with good agricultural practices.

Residue Chemistry Data

Residue chemistry data are necessary only if the submitted toxicology studies indicate that additional Tier II or II toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicate that the product is of low mammalian toxicity; therefore, Tier II or III data were not required.

Acceptable chemistry data are necessary only if the submitted toxicology studies indicate that additional Tier II or III toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicate that the product is of low mammalian toxicity; therefore, Tier II or III data were not required.

Based on the information considered, the Agency concludes that the establishment of a tolerance for the active ingredient Occlusion Bodies of the Granulosis Virus of *Cydia pomonella* is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register,** file written objections

and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 2F4090/R2154] (including any objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [PP 2F4090/R2154], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:
opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 21, 1995.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1148, to read as follows:

§ 180.1148 Occlusion Bodies of the Granulosis Virus of Cydia pomenella; tolerance exemption.

An exemption from the requirement of a tolerance is established for residues of the microbial pest control agent Occlusion Bodies of the Granulosis Virus of *Cydia pomonella* (codling moth) in or on all raw agricultural commodities.

[FR Doc. 95–20307 Filed 8–15–95; 8:45 am]
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40 CFR Part 180

[PP 4E4410/R2160; FRL–4971–2]

RIN 2070–AB78

Plant Pesticide Inert Ingredient Phosphinothricin Acetyltransferase (PAT) and the Genetic Material Necessary for Its Production (Plasmid Vector pCIBP3064) in Corn; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the plant pesticide inert ingredient phosphinothricin acetyltransferase and the genetic material necessary for its production (plasmid vector pCIB3064) in corn. A request for an exemption from the requirement of a tolerance was submitted by the Ciba-Geigy Corp. (Ciba Seed). This regulation eliminates the need to establish a maximum permissible level for residues of this plant pesticide inert ingredient in the raw agricultural commodities of field corn, sweet corn, and popcorn.

EFFECTIVE DATE: Effective on August 16, 1995.

ADDRESSES: Written objections and hearing requests, identified bythe document control number [PP 4E4410/R2160], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW.,